

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**SHIRE LLC, et al.,** :

:

**Plaintiffs,** : Civil Action No. 2:11-cv-03781 (SRC)(CLW)

:

**v.** : (CONSOLIDATED)

:

**AMNEAL PHARMACEUTICALS, LLC,** : **OPINION**

:

**et al.,** :

**Defendant.** :

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## I. Introduction

Plaintiffs Shire LLC and Shire Development LLC (collectively “Shire”) oppose the motion. (Docket Entry No. 391 (“Pl. Opp.”)). On September 30, 2013, Defendants filed a reply brief. (Docket Entry No. 396, (“Def. Reply”)). On October 22, 2013, the Court held oral argument on the record. (Docket Entry No. 425, “Transcript”). The Court has reviewed the submissions in favor of and in opposition to the motion and considered the arguments raised by the parties during oral argument. For the reasons set forth below, the motion is hereby **DENIED.**

## **II. Discussion**

### **A. Legal Standard**

Local Patent Rule 3.7 (“Rule 3.7”) of the Local Rules of Civil Procedure, of the United States District Court, for the District of New Jersey, governs “[a]mendments of any contentions, disclosures, or other documents required to be filed or exchanged....” Where a party seeks leave to amend its invalidity contentions, it must do so “by order of the Court upon a timely application and showing of good cause.” Id. The application shall disclose whether the adverse party consents or objects. Furthermore, Rule 3.7 only permits amendment “absent undue prejudice to an adverse party.” Id. Thus, pursuant to Rule 3.7, a court may permit a party to amend its invalidity contentions provided the following three elements are established: (1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party.

In the context of patent litigation, Federal Circuit precedent governs the interpretation of local patent rules because such issues are “intimately involved in the substance of enforcement of the patent right.” O2 Micro International Ltd. v. Monolithic Power Systems, Inc., 467 F.3d 1355, 1364 (Fed. Cir. 2006). The Local Patent rules “exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case.” Computer Accelerations Corp. v. Microsoft Corp., 503 F.Supp.2d 819, 822 (E.D. Tex. 2007). Specifically, the patent rules governing contentions are designed to encourage parties to provide “early notice of their infringement and invalidity contentions and to proceed with diligence in amending those contentions when new information comes to light in the course of discovery.” O2 Micro, 467 F.3d at 1365-66. The local rules “seek to balance the right to develop new information in discovery with the need for certainty as to the legal theories.” Id.

While some leniency is extended in amending contentions, the local rules require “parties to crystallize their theories of the case early in the litigation.” Id. at 1364.

Amendments to infringement and invalidity contentions are not granted as liberally as requests for amendments to pleadings, in part, because “the philosophy behind amending claim charts is decidedly conservative and designed to prevent the ‘shifting sands’ approach,” to a party’s contentions. King Pharmaceuticals, Inc. v. Sandoz, Inc., Civil No. 08-5974, 2010 WL 2015258, at \*4 (D.N.J. May 20, 2010); Cf. FED. R. CIV. P. 15(a)(2). Particularly, in the District of New Jersey, the Local Patent Rules emphasize “*ultra* early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act.” Sanofi-Aventis v. Barr Labs., Inc., 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (emphasis in original).

## **B. Parties’ Arguments**

### **a. Defendants’ Arguments in Support of the Motion**

Defendants propose to supplement their contentions with two additional bases for invalidity: 1) certain documents produced by Plaintiffs and third parties demonstrate that a commercial embodiment covered by the claims of Patent No. 7,659,253 (“the ‘235 patent”) was sold or offered for sale prior to the earliest effective filing of the aforementioned patent (“the On-Sale Bar”); and 2) a reference by R.A. Houghten entitled “Use of 10% sulfuric acid/diozane for removal of N- $\alpha$ -tertiary-butyloxycarbonyl group during solid phase peptide synthesis” (“the Houghten reference”). (Motion, p 1).

Defendants contend they diligently sought and reviewed relevant, non-public documents from the non-party inventors and from companies that worked with Plaintiffs on the lisdexamphetamine dimesylate (“LDX”) project. Beginning in April 2012, Defendants issued document subpoenas and worked with counsel to resolve issues related to the document

production. However, Defendants now contend the documents, from which the On-Sale Bar claim originates, were not produced until January and May of this year. (Id. at 10).

Similarly as to the Houghten reference, Defendants contend that only recently they became aware of its existence during the preparation for the deposition of Dr. Bernard Paul. (Id. at 13). Defendants point to the aforementioned deposition as confirmation that Dr. Paul employed various types of reactants also disclosed in Houghten to deprotect lisdexamphetamine and create LDX.

Defendants' further contend that the discovery of prior art constitutes good cause to amend because the information was not made available to Defendants until the final stages of discovery and could not locate the Houghten reference during their initial search.. (Id. at 14, 19).

Lastly, as to the On-Sale Bar, Defendants argue that Plaintiffs would not be required to expend additional resources as a result of their amendments because the contentions at issue comprise just seven pages and the basis of the proposed amendments are Plaintiffs' own documents. (Id. at 15). Similarly, permitting Defendants' amendments with respect to the Houghten reference will present no prejudice because Houghten "merely supplements an invalidity theory already in the case," a theory Defendants allege was known to Plaintiffs as early as 2003. (Id. at 20.).

#### **b. Shire's Arguments in Opposition to the Motion**

Shire argues that Defendants' motion should fail because they have demonstrated no diligence and do not have good cause to amend. (Pl. Opp. at 6). Shire submits that "good cause" to amend requires diligent investigation. (Id. at 6). The information which forms the basis for Defendants' motion was available to all defendants prior to commencement of the litigation. (Id.

at 4). As such, Shire argues that Defendants have failed to demonstrate diligence and, consequently, their motion must fail. (*Id.* at 9).

Additionally, Shire argues that it would be unduly prejudiced by Defendant's late supplementation because fact discovery has ended; opening expert reports are due; and the proposed amendment with regard to the Houghten reference applies to every asserted claim of every patent-in-suit introducing new arguments heretofore not raised.

### **C. Analysis**

#### **a. Timeliness**

The Court finds that Defendants' application is not timely. The Federal Circuit has emphasized the importance of the "timely application" element by recognizing that "if the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery in trial preparation." O2 Micro, 467 F.3d at 1366.

In this case, Defendants' state they only recently discovered the information giving rise to this motion.<sup>1</sup> However, the summary of documents produced by Shire on May 21, 2012 indicates that Defendants had access to the information, or documentation that should have led them to it earlier than they now claim. (Pl. Opp., App. A).<sup>2</sup> The Court finds these facts to cut against Defendants' assertion that the On-Sale Bar claim could not have been brought until September 2013.

This Court previously stated that a similarly situated moving party has "an obligation to conduct a public search for all relevant prior art in a diligent manner." Jazz Pharms., Inc. v.

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<sup>1</sup> Defendants assert they had no way of obtaining evidence of the anticipatory sale prior to January and May of 2013 and similarly contend the significance of the Houghten reference did not become immediately apparent until the deposition of Dr. Bernard Paul in July 2013.

<sup>2</sup> In May of 2012, Shire provided documentation identifying AMRI, Cambrex, and Patheon as providing manufacturing services. (*Id.*).

Roxane Labs., Inc., 2012 U.S. Dist. LEXIS 107408 (D.N.J. July 30, 2012). The Houghten reference is not a confidential document and is available to the public. Prior to the commencement of the litigation, the Defendants were required to file Abbreviated New Drug Applications (“ANDAs”) with the FDA, including certifications that the patents-in-suit were invalid or not infringed. Each “ANDA” defendant was required to perform prior art searches to develop a basis for alleging invalidity of the patents-in-suit to support their claims to the FDA. On July 26, 2012 Defendant Mylan filed invalidity contentions citing the second addition of Green & Wuts, “Protective Groups in Organic Synthesis.” The third addition of this article references Houghten. Defendants provide no explanation as to why their public search failed to uncover the public document.

In Jazz, this Court found that a similar motion was untimely because the movant failed to provide justification for a five (5) month delay in filing. (Id. at 15). Adopting *arguendo* Defendants’ timeline, Defendants waited more than a month to request Shire’s consent to supplement their invalidity contentions. The parties appeared before this Court on August 1, 2013, an event in between Defendants’ newly discovered information and their formal request to supplement their invalidity contentions. Here, the Court evaluates Defendants’ delay relative to the maturity of this case and finds that Defendants have not provided a sufficient justification for the delay.

#### **b. Good Cause**

In addition to considering if the motion is timely, the Court must also find that good cause exists. Rule 3.7 provides a non-exhaustive list, in its subsections, of circumstances that may constitute a showing of good cause. Defendants seek to amend their Invalidity Contentions under subsection (b), which permits amendment where there has been “recent discovery of

material prior art despite earlier diligent search.” O2 Micro, 467 F.3d at 1366. Shire argues that Defendants failed to conduct a diligent search.

In order to illustrate good cause, there must be a showing of diligence. Id. The “burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence.” Id. Specifically, a good cause showing “requires diligence throughout the discovery process and that the moving party not only must act promptly upon discovery of new [information], but also must establish that it was diligent in its search.” West v. Jewelry Innovations, Inc., Civil No. 07-1812, 2008 WL 4532558, at \*2 (N.D. Cal., Oct. 8, 2008). Thus, in addition to considering if the application to the Court subsequent to discovery was timely, the court must consider if the movant “was diligent in discovering the basis for the proposed amendment.” West, 2008 WL 4532558, at \*2.

As to the On-Sale Bar, Defendants submit that they were only able to uncover information alleging three (3) potential offers for sale after combing through 2.3 million pages of document production. (Motion at 2). Specifically, Defendants contend their request to supplement is solely based on recently produced, non-public documents. (Def. Reply at 4). At oral argument Defendants asserted that this information was available but withheld by Shire in an attempt to frustrate their position. Defendants also submit that it was a difficult task to identify and assemble the information in a recognizable form to assert the claim.

Turning to the Houghten reference, Shire contends Defendants are on constructive notice of Houghten because it is a publicly-available journal article and was identified in Shire’s document production of May 2012. Defendants respond claiming that is an unfair assumption because of the sheer volume of documents produced. As discussed in the previous section, avenues were available by which Defendants could arrive at the Houghten reference prior to the

deposition of Dr. Paul. Regardless of the form in which it was provided to Defendants, Shire disclosed documentation pertaining Houghten. The Court finds Defendants' argument unpersuasive.

Defendants failed to illustrate that they conducted a diligent search. The alleged prior art, as it relates to the On-Sale Bar, is referenced in various portions of the document production. Defendants rest on Shire's alleged lack of cooperation as a basis for why they filed the motion late in the process. The Court finds that argument unpersuasive as well. It is Defendants' burden to conduct a diligent search for prior art. This includes taking reasonable measures to review documents relating to the patents-in-suit and tailoring its public search appropriately. The Court finds Defendants have failed to carry their burden in illustrating they conducted a diligent search. Consequently Defendants have not demonstrated good cause to amend their Invalidity Contentions.

**c. Undue Prejudice to Non-Movant**

As to the undue prejudice prong, the Federal Circuit has made it clear that the Court only needs to consider undue prejudice if the moving party's application was timely and satisfies the good cause requirement. O2 Micro, 467 F.3d at 1368. Courts in this District, however, have addressed this prong where the movant has proffered a reason, albeit unpersuasive, for the untimeliness of the application and/or failure to illustrate good cause. See King, 2010 WL 2015258, at \*4. This Court must consider whether permitting the proposed amendments would significantly delay the resolution of the dispute. Id. at 5. In particular, the Court must look to the present stage of the litigation and the impact of permitting an amendment on the non-moving party's trial strategy. Id. Here, fact discovery was complete as of September 20, 2013 and opening expert reports were due on October 4, 2013.



Granting Defendants' motion will likely unduly prejudice Shire. Claim construction briefing and the Markman are complete. Shire has relied on Defendants' previous invalidity contentions for a year in preparing its case. Permitting an amendment now would likely cause undue prejudice to Shire by requiring additional discovery and experts. It follows that this additional discovery would not only delay the case but also force Shire to abandon the strategy it has been developing for the past year. Such a delay will unduly prejudice Shire. Defendants' motion must be denied.

#### **IV. Conclusion**

For the reasons set forth above, the undersigned hereby **DENIES** Defendants' Motion. An appropriate order shall follow.

s/Cathy L. Waldor  
**CATHY L. WALDOR**  
**UNITED STATES MAGISTRATE JUDGE**

Dated: December 23, 2012